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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,196	03/26/2004	Barry N. Gellman	62881C1(71589)	2937

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EXAMINER

SWEET, THOMAS

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/811,196	Applicant(s) GELLMAN, BARRY N.	
	Examiner Thomas J. Sweet	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-54 is/are pending in the application.
- 4a) Of the above claim(s) 48-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/26/04, 6/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 35-47 only) in the reply filed on 10/26/2005 is acknowledged. The traversal is on the ground(s) that It does not provided a serious burden on the examiner and the subject matter of claims 52-54 because of the relationship of the subject matter to Group I. This is not found persuasive because Examining claims 48-54 requires a broader search in areas beyond group I and additional consideration. Also, the addition request for examination of claims 52-54 is denied as these claims were not presented in independent form as a combination as originally claim (and if they had been they would have been restricted as an additional Group to a combination not requiring particulars of the subcombination) so, claim 48 is an evidence claim that the particulars of Group I are not necessary for patentability of the combination (actually a subcombination).

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 3/26/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the search report US03/32286 referred to therein has not been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is

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appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-40 and 42-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 9 and 14 of U. S. Patent No. 6733536. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current applications claims 35-40 and 42-47 are broader than and therefore encompass claims 1, 5, 6, 9 and 14 of the parent U. S. Patent No. 6733536.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Datta et al (US PG pub 20030045924). Datta et al discloses a medical device (fig. 10) for use within a body lumen of a patient, the device comprising: a stent comprising: a first anchoring segment (730)

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locatable on the proximal side of the external sphincter (see fig.8), the first anchoring segment having a distal end terminating on the proximal side of the external sphincter when the device is placed within the body of the patient; a second anchoring segment (740) locatable on the distal side of the external sphincter (see fig.8), the second anchoring segment having a proximal end terminating on the distal side of the external sphincter when the device is placed within the body of the patient; and a connecting segment (750) locatable in the external sphincter when the device is placed within the body of the patient (see fig.8), the connecting segment disposed between and coupling together the first anchoring segment and the second anchoring segment; and a removal segment attached to the stent (several components can be categorized as an attached removal segment including 715 which degrades facilitating removal, 712 which breaks down to granules to be flushed out of the system and the end at 702 is fully capable of being grabbed or hooked to withdrawn the device from the device from the urethra).

With regard to claims 36 and 44, at least one (both) of the first anchoring segment and the second anchoring segment comprises a coil having a plurality of windings (both are in fig. 10).

With regard to claims 37 and 45, the first anchoring segment comprises a coil having a plurality of windings and the second anchoring segment comprises a coil having a plurality of windings and the windings of the first anchoring segment and the second anchoring segment are sized and configured to progressively uncoil upon application of a continuous tensile force to the removal segment (inherent since the structure is the same, the windings are not connected and the end at 702 can be grabbed or hooked as described above).

With regard to claims 38 and 46, at least one of the first anchoring segment and the second anchoring segment defines a lumen (hollow coil).

With regard to claim 39, at least one (both) of the first anchoring segment, the second anchoring segment, and the connecting segment further comprise an inner core 712 and an outer coating covering at least a portion of the inner core 715.

With regard to claim 40, the proximal end of the first anchoring segment and the distal end of the second anchoring segment include one or more hooks (the ends are ends of winding which are shaped as hooks) to permit connection to a delivery system (by rapping around the delivery device).

With regard to claim 41, the proximal end of the first anchoring segment comprises an atraumatic tip (the tip at far end from 702 is rounded and looped over on itself which inherently is atraumatic in that it is blunt and less likely to damage the wall than a terminated tip).

With regard to claims 42 and 47, at least one (both) of the first anchoring segment and the second anchoring segment comprises a cross-sectional shape which is circular.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs



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